

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tanya Arenson on 7/22/2008.

The application has been amended as follows:

Please replace the paragraph on page 64 starting at line 13 to line 31 with the following:

In addition to colon cancer, prostate cancer demonstrated moderate to high levels of HIP1 expression (FIG. 2h), while benign epithelia did not express HIP1. To study the aberrant HIP1 expression in more detail, three prostate tissue microarrays containing a total of 853 tissue spots from 114 patients with localized prostate cancer were stained with the HIP1 monoclonal antibodies. These samples included benign prostate tissue, prostatic intraepithelial neoplasia (PIN) and prostate cancer (PCa). In addition, a separate tissue microarray that contained 135 tumor samples from 14 patients with hormone-refractory metastatic PCa was examined for HIP1 expression. As in the colon, striking differences were noted in staining between neoplastic and benign epithelia. PCA from the prostate tissue microarray demonstrated high HIP1 expression juxtaposed to non-HIP1 expressing benign prostatic epithelium. 95% of normal epithelium samples did not express HIP1. The remaining 5% had weak levels of expression and there was no moderate or high expression in any of the normal epithelia examined. Among neoplastic lesions, the precursor of prostate cancer, PIN, had the lowest number of samples with moderate or strong levels of HIP1 expression (25% of the 230 samples). Localized PCa had an intermediate number (51% of the 463 samples) and

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metastatic prostate cancer had the highest number of samples expressing moderate to strong levels of HIP1 (70% of the 135 samples). This difference in levels of HIP1 in progressively more advanced PCA was statistically significant (FIG. 3b, Pearson's chi-squared,  $P < 0.0001$ ).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919.

The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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